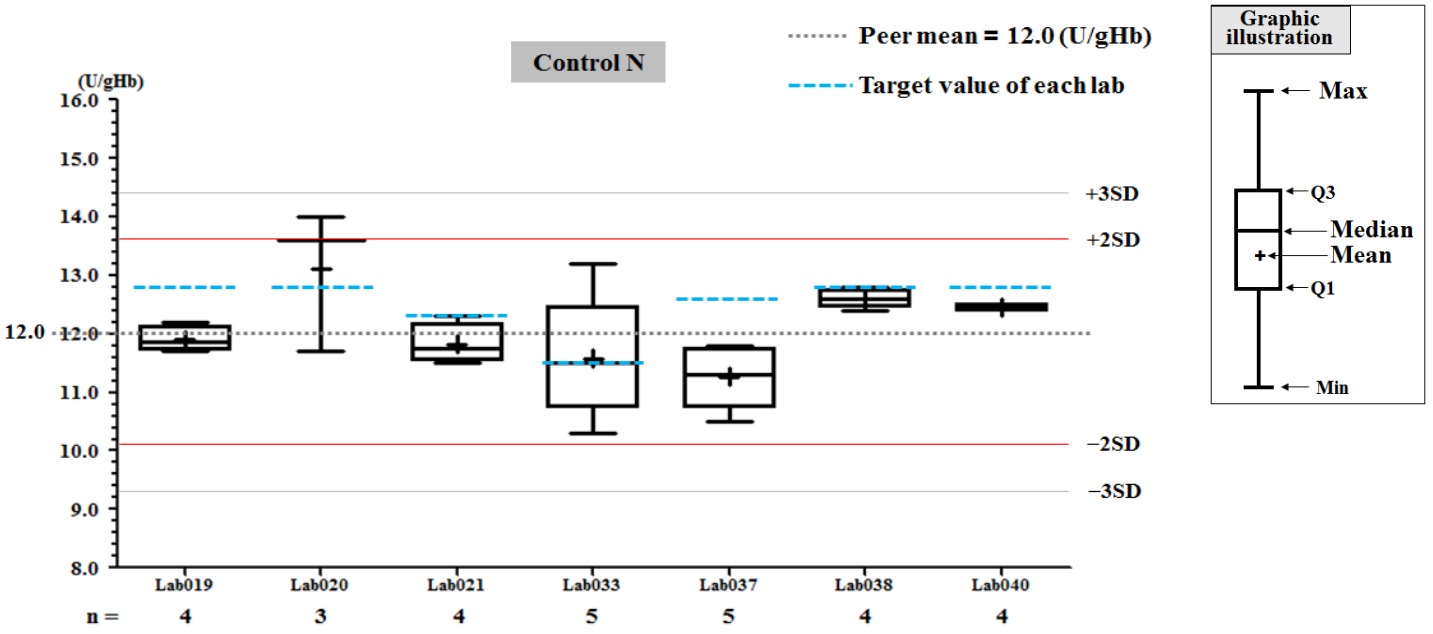
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - December 2016 -

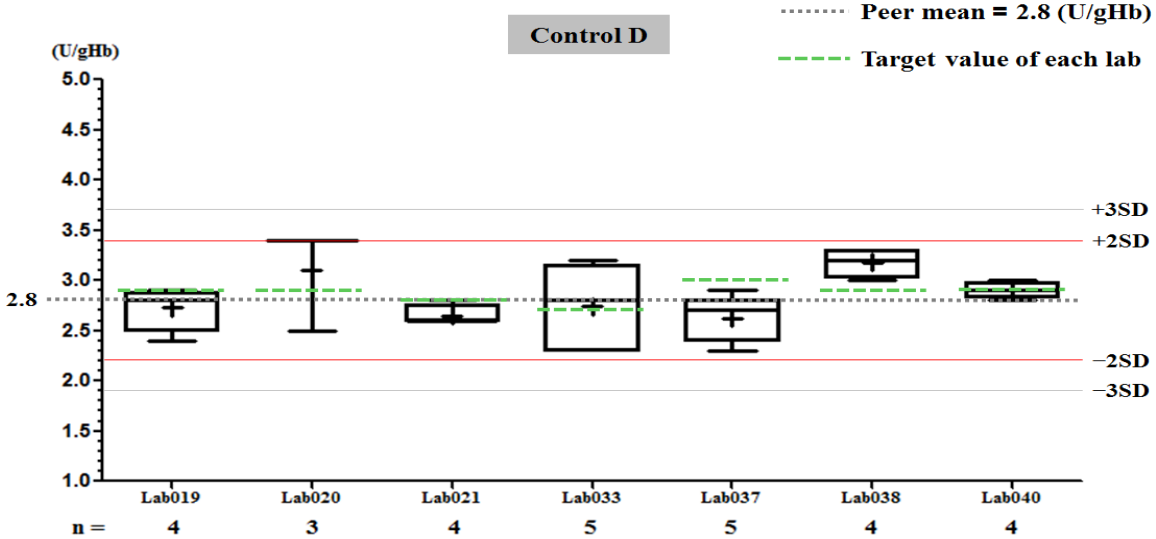
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	7	7
Received results number (n)	29	29
Median	11.8 (U/gHb)	2.8 (U/gHb)
Mean	12.0 (U/gHb)	2.8 (U/gHb)
SD	0.8	0.3
CV	6.7%	10.7%
Range of G6PD	10.3 ~ 14.0 (U/gHb)	2.3 ~ 3.4 (U/gHb)
Range of Hb	2.1 ~ 2.8 (g/dL)	2.7 ~ 3.6 (g/dL)

*The statistic results are calculated from all labs reported in this month
** G6PD Method = AMP reagent kit, 37°C

II. The distribution of G6PD reported for each lab in this survey





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QC Chart of Internal Quality Control (IQC)for G6PD Quantitative Test

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Print Table

Lab019

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2016/12)	CUM (2016/07/01~2016/12/31)	Month (2016/12)	CUM (2016/07/01~2016/12/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	11.9	12.1	2.7	2.9
SD	0.2	0.6	0.2	0.2
CV (%)	1.7	5.0	7.4	6.9
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	10.4	15.4	21.7	13.8
TEa (%)	20	20	20	20
σ	>6	2.9	1.8	2.9

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE : Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

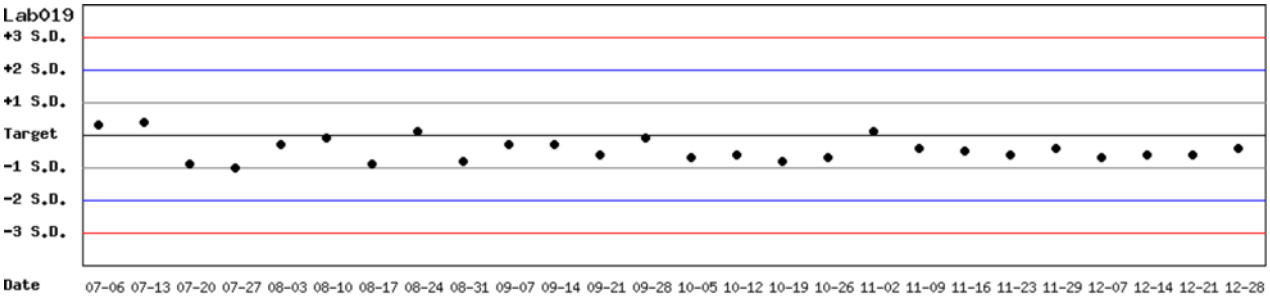
Month : 2016 12 Change ; Cumulative : from 2016 07 01 to 2016 12 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-07-01 to 2016-12-31 ; Target : 12.8 ; SD : 1.60

Lab019



Month : 2016 12 Change ; Cumulative : from 2016 07 01 to 2016 12 31 Change

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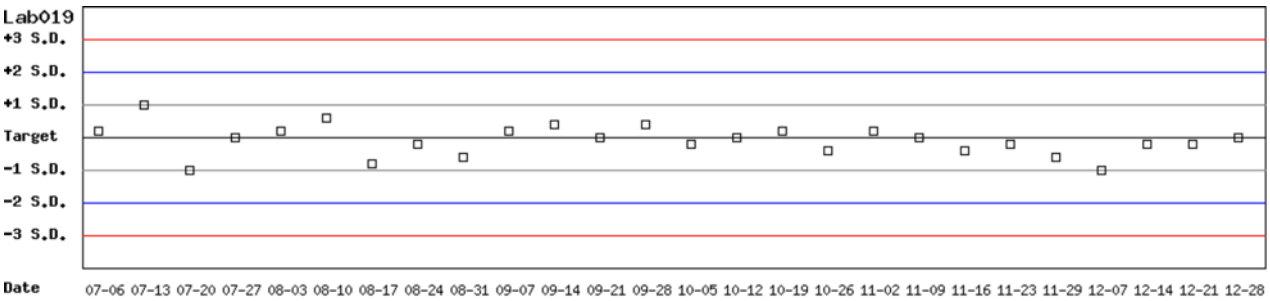
Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-07-01 to 2016-12-31 ; Target : 2.9 ; SD : 0.50

Lab019



Month : 2016 12 Change ; Cumulative : from 2016 07 01 to 2016 12 31 Change

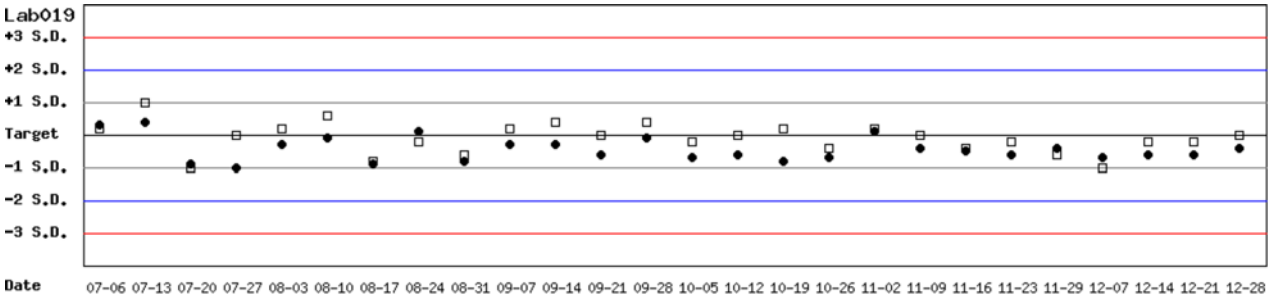
[TOP]

Control N and **Control D SDI**
QC Chart

Lot No.: AC1203N ; Duration : 2016-07-01 to 2016-12-31 ; Target : 12.8 ; SD : 1.60 (●)

Lot No.: AC1203D ; Duration : 2016-07-01 to 2016-12-31 ; Target : 2.9 ; SD : 0.50 (□)

Lab019



Month : 2016 | 12 Change ; Cumulative : from 2016 | 07 | 01 to 2016 | 12 | 31 Change

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Peer Group Statistics (Table 1)

Select LotNo：AC1203N (2014-01-01 ~ 2100-12-31) Change

Select Reagent Kit：2 - AMP Change

Print Table 1

Monthly

Month : 2016 12 Change

		Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab019	2	12.8	11.9	4	0.2	1.7	10.4	20	>6	2.9	2.7	4	0.2	7.4	21.7	20	1.8
Lab020	2	12.8	13.1	3	1.2	9.2	20.7	20	1.9	2.9	3.1	3	0.5	16.1	39.2	20	0.8
Lab021	2	12.3	11.8	4	0.3	2.5	9.1	20	>6	2.8	2.7	4	0.1	3.7	11.0	20	4.4
Lab033	2	11.5	11.6	5	1.1	9.5	19.8	20	2.0	2.7	2.7	5	0.4	14.8	29.6	20	1.4
Lab037	2	12.6	11.3	5	0.5	4.4	19.2	20	2.2	3.0	2.6	5	0.2	7.7	28.7	20	0.9
Lab038	2	12.8	12.6	4	0.2	1.6	4.7	20	>6	2.9	3.2	4	0.2	6.3	22.8	20	1.5
Lab040	2	12.8	12.5	4	0.1	0.8	3.9	20	>6	2.9	2.9	4	0.1	3.4	6.9	20	5.9
Total	-	-	12.0	29	0.8	6.7	-	-	-	-	2.8	29	0.3	10.7	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE：Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

[TOP]

Cumulative

Cumulative : from 2014 02 01 to 2016 12 31 Change

		Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab017	2	14.2	13.8	36	1.6	11.6	26.0	20	1.5	3.3	3.9	36	1.4	35.9	90.0	20	0.1
Lab018	2	10.9	10.9	113	1.3	11.9	23.9	20	1.7	2.5	2.6	113	0.9	34.6	73.2	20	0.5
Lab019	2	12.8	12.2	149	1.1	9.0	22.7	20	1.7	2.9	2.8	149	0.4	14.3	32.0	20	1.2
Lab020	2	12.8	12.0	10	1.4	11.7	29.6	20	1.2	2.9	2.9	10	0.5	17.2	34.5	20	1.2
Lab021	2	12.3	13.5	88	1.0	7.4	24.6	20	1.4	2.8	3.2	88	0.3	9.4	33.0	20	0.6
Lab022	2	14.2	11.5	63	1.2	10.4	39.9	20	0.1	3.3	2.9	63	0.3	10.3	32.8	20	0.8
Lab024	2	11.6	11.1	58	1.2	10.8	25.9	20	1.5	2.7	2.7	58	0.3	11.1	22.2	20	1.8
Lab026	2	11.6	11.5	212	1.6	13.9	28.7	36	2.5	2.7	2.8	212	0.5	17.9	39.4	36	1.8
Lab027	2	12.3	11.8	147	1.6	13.6	31.2	20	1.2	2.9	2.7	147	0.5	18.5	43.9	20	0.7
Lab028	2	13.2	13.6	309	1.2	8.8	20.7	20	1.9	3.2	3.3	309	0.5	15.2	33.4	20	1.1
Lab031	2	12.8	10.4	89	1.5	14.4	47.6	20	0.1	2.9	2.5	89	0.5	20.0	53.8	20	0.3
Lab032	2	12.3	11.5	222	1.9	16.5	39.5	20	0.8	2.9	2.7	222	0.5	18.5	43.9	20	0.7
Lab033	2	11.5	12.0	139	1.0	8.3	21.0	20	1.9	2.7	2.9	139	0.3	10.3	28.1	20	1.2
Lab034	2	12.8	12.3	82	0.7	5.7	15.3	20	2.8	2.9	3.0	82	0.3	10.0	23.4	20	1.7
Lab035	2	12.8	12.4	55	0.7	5.6	14.4	20	3.0	2.9	2.8	55	0.3	10.7	24.9	20	1.5
Lab037	2	12.6	12.3	53	1.2	9.8	21.9	20	1.8	3.0	3.0	53	0.4	13.3	26.7	20	1.5
Lab038	2	12.8	12.7	59	1.0	7.9	16.5	20	2.4	2.9	3.2	59	0.5	15.6	41.6	20	0.6
Lab040	2	12.8	12.1	17	0.5	4.1	13.7	20	3.5	2.9	2.6	17	0.4	15.4	41.1	20	0.6
Total	-	-	12.1	1901	1.6	13.2	-	-	-	-	2.9	1901	0.6	20.7	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE：Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

[TOP]

Reagent Kit	Reagent Code
AMP	2

Peer Group Statistics (Table 2)

Select LotNo：AC1203N (2014-01-01 ~ 2100-12-31) Change

Select Reagent Kit：2 - AMP Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AC1203N)															
		Month (2016/12)								CUM (2014/02/01~2016/12/31)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab017	2	14.2	-	0	-	-	-	20	-	14.2	13.8	36	1.6	11.6	26.0	20	1.5
Lab018	2	10.9	-	0	-	-	-	20	-	10.9	10.9	113	1.3	11.9	23.9	20	1.7
Lab019	2	12.8	11.9	4	0.2	1.7	10.4	20	>6	12.8	12.2	149	1.1	9.0	22.7	20	1.7
Lab020	2	12.8	13.1	3	1.2	9.2	20.7	20	1.9	12.8	12.0	10	1.4	11.7	29.6	20	1.2
Lab021	2	12.3	11.8	4	0.3	2.5	9.1	20	>6	12.3	13.5	88	1.0	7.4	24.6	20	1.4
Lab022	2	14.2	-	0	-	-	-	20	-	14.2	11.5	63	1.2	10.4	39.9	20	0.1
Lab024	2	11.6	-	0	-	-	-	20	-	11.6	11.1	58	1.2	10.8	25.9	20	1.5
Lab026	2	11.6	-	0	-	-	-	36	-	11.6	11.5	212	1.6	13.9	28.7	36	2.5
Lab027	2	12.3	-	0	-	-	-	20	-	12.3	11.8	147	1.6	13.6	31.2	20	1.2
Lab028	2	13.2	-	0	-	-	-	20	-	13.2	13.6	309	1.2	8.8	20.7	20	1.9
Lab031	2	12.8	-	0	-	-	-	20	-	12.8	10.4	89	1.5	14.4	47.6	20	0.1
Lab032	2	12.3	-	0	-	-	-	20	-	12.3	11.5	222	1.9	16.5	39.5	20	0.8
Lab033	2	11.5	11.6	5	1.1	9.5	19.8	20	2.0	11.5	12.0	139	1.0	8.3	21.0	20	1.9
Lab034	2	12.8	-	0	-	-	-	20	-	12.8	12.3	82	0.7	5.7	15.3	20	2.8
Lab035	2	12.8	-	0	-	-	-	20	-	12.8	12.4	55	0.7	5.6	14.4	20	3.0
Lab037	2	12.6	11.3	5	0.5	4.4	19.2	20	2.2	12.6	12.3	53	1.2	9.8	21.9	20	1.8
Lab038	2	12.8	12.6	4	0.2	1.6	4.7	20	>6	12.8	12.7	59	1.0	7.9	16.5	20	2.4
Lab040	2	12.8	12.5	4	0.1	0.8	3.9	20	>6	12.8	12.1	17	0.5	4.1	13.7	20	3.5
Total	-	-	12.0	29	0.8	6.7	-	-	-	-	12.1	1901	1.6	13.2	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE：Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2016 12 Change Cumulative : from 2014 02 01 to 2016 12 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2016/12)								CUM (2014/02/01~2016/12/31)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab017	2	3.3	-	0	-	-	-	20	-	3.3	3.9	36	1.4	35.9	90.0	20	0.1
Lab018	2	2.5	-	0	-	-	-	20	-	2.5	2.6	113	0.9	34.6	73.2	20	0.5
Lab019	2	2.9	2.7	4	0.2	7.4	21.7	20	1.8	2.9	2.8	149	0.4	14.3	32.0	20	1.2
Lab020	2	2.9	3.1	3	0.5	16.1	39.2	20	0.8	2.9	2.9	10	0.5	17.2	34.5	20	1.2
Lab021	2	2.8	2.7	4	0.1	3.7	11.0	20	4.4	2.8	3.2	88	0.3	9.4	33.0	20	0.6
Lab022	2	3.3	-	0	-	-	-	20	-	3.3	2.9	63	0.3	10.3	32.8	20	0.8
Lab024	2	2.7	-	0	-	-	-	20	-	2.7	2.7	58	0.3	11.1	22.2	20	1.8
Lab026	2	2.7	-	0	-	-	-	36	-	2.7	2.8	212	0.5	17.9	39.4	36	1.8
Lab027	2	2.9	-	0	-	-	-	20	-	2.9	2.7	147	0.5	18.5	43.9	20	0.7
Lab028	2	3.2	-	0	-	-	-	20	-	3.2	3.3	309	0.5	15.2	33.4	20	1.1
Lab031	2	2.9	-	0	-	-	-	20	-	2.9	2.5	89	0.5	20.0	53.8	20	0.3
Lab032	2	2.9	-	0	-	-	-	20	-	2.9	2.7	222	0.5	18.5	43.9	20	0.7
Lab033	2	2.7	2.7	5	0.4	14.8	29.6	20	1.4	2.7	2.9	139	0.3	10.3	28.1	20	1.2
Lab034	2	2.9	-	0	-	-	-	20	-	2.9	3.0	82	0.3	10.0	23.4	20	1.7
Lab035	2	2.9	-	0	-	-	-	20	-	2.9	2.8	55	0.3	10.7	24.9	20	1.5
Lab037	2	3.0	2.6	5	0.2	7.7	28.7	20	0.9	3.0	3.0	53	0.4	13.3	26.7	20	1.5
Lab038	2	2.9	3.2	4	0.2	6.3	22.8	20	1.5	2.9	3.2	59	0.5	15.6	41.6	20	0.6
Lab040	2	2.9	2.9	4	0.1	3.4	6.9	20	5.9	2.9	2.6	17	0.4	15.4	41.1	20	0.6
Total	-	-	2.8	29	0.3	10.7	-	-	-	-	2.9	1901	0.6	20.7	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE：Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2016 12 Change Cumulative : from 2014 02 01 to 2016 12 31 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2